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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,317	03/28/2001	Patrick L. Coleman	56066USA1A.002	4377

32692 7590 06/17/2003

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EXAMINER
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ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/17/2003

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 06-03-03

Application Number: 09/819,317
Filing Date: March 28, 2001
Appellant(s): COLEMAN ET AL.

Loren D. Albin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 28, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1, 3-11, 23 and 26 stand or fall together because appellant's brief expressly states that the claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

WO 99/53319	Halverson et al	10-1999
US 4,589,965	Kreisher	05-1986

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-11, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halverson et al (WO 99/53319) in view of Kreisher et al (U.S. Patent 4,589,965).

Halverson teaches a method of transferring molecules to a laminate (see page 6, lines 12-17) comprising:

(a) providing a laminate (see page 3) comprising

i) a shrinkable polymeric substrate having a projected surface area and a topographical surface area (see page 3, lines 7-16)

ii) a hydrogel disposed on at least a portion of the substrate (see page 8, lines 9-18, page 9, lines 8-35 and page 10, lines 5-9),

(b) contacting the laminate with the molecules to be affixed (see page 6, lines 12-17 and page 17, lines 19-35)

(c) transferring said molecules to the laminate (see page 17, lines 19-35)

(d) removing the laminate from the transfer process (see page 17, lines 19-35)

(e) shrinking the laminate so that the topographical surface area is greater than the projected surface area (see page 3, lines 7-31, page 11, lines 16-22, page 37, claims 8-10).

Halverson teaches the use of azlactone copolymers (see page 12, line 33-35). Halverson further teaches the use of a masking layer (see page 13, lines 30-33) as well as coating nucleic acids, amino acids and proteins onto the laminate (see page 7, lines 12-15). Halverson further teaches detection of the molecules transferred onto the laminate (see example 17, pages 33-35). Halverson further teaches the use of covalently bonded linkage moieties (see page 6, line 13).

Halverson does not teach transfer of the molecules using a matrix to the laminate.

Kreisher et al (U.S. Patent 4,589,965) teaches electroblot transfer of molecules from a matrix to an immobilizing material (see column 2, lines 3-67). In particular, Kreisher teaches the steps of

(b) contacting the matrix with the immobilizing material (see column 2, lines 35-43)

(c) transferring the molecules from the matix to the immobilizing material (see column 2, lines 55-60)

(d) removing the matrix from the immobilizing material (column 5, lines 61-62).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to transfer the molecules onto the laminates of Halverson using the electroblot method of Kreisher since Halverson expressly states "'Affix' shall include any mode of attaching reactants to a substrate. Such modes shall include, without limitation, covalent and ionic binding, adherence, such as with an adhesive, and physical entrapment within a substrate (page 6, lines 12-14)". An ordinary practitioner, faced with the express suggestion of Halverson to "affix" the molecules by any desirable method, would have been motivated to select the method of Kreisher since Kreisher states "Therefore it is a principal advantage of the present invention to provide a rapid and efficient method for electroblotting (see column 2, lines 19-21)." Kreisher continues a sentence later to note "It is an additional object of the present invention to provide a method as aforesaid which obtains high resolution and absence of diffusion (see column 2, lines 25-27)." An ordinary practitioner would have been motivated to follow the express suggestion of Halverson to affix the molecules using multiple modes and to utilize the mode of Kreisher since Kreisher indicates that the electroblotting method is fast, it is efficient and it has high resolution, all characteristics desirable to Halverson, in particular the high resolution.

(11) Response to Argument

Introduction

In order to understand the issues in this application, the underlying technology will be briefly discussed. The claimed invention is drawn to methods of manufacturing arrays. The current application is based on an invention, by Halverson (WO 99/53319), that shares three common inventors with the current application, of arrays which can be made smaller. These arrays are made on heat shrinkable films or laminates. Halverson teaches generically affixing macromolecules such as nucleic acids to these arrays (see abstract and page 6, lines 12-14). Once the macromolecules are affixed onto the heat shrinkable films, the films are subjected to conditions which will result in shrinkage. This technique, taught in WO 99/53319, simplifies array manufacture by permitting the artisan to affix or attach the molecules at a low density, yet ultimately obtain a higher density array due to the shrinkage of the laminate or heat shrinkable film to which the array is affixed. The current claims differ from the Halverson (WO 99/53319) in that the array being transferred is derived from a matrix.

Prima facie case

The prima facie case is based upon two references, Halverson (WO 99/53319) and Kreisher (U.S. Patent 4,589,965). Halverson teaches each and every limitation of the invention except for the use of a matrix as the source of the transfer. Kreisher represents an exemplification of what is well known and very old in the art of biotechnology. Kreisher teaches that there is a strong desire to transfer material from

matrices, such as gels onto solid supports in order to permit detection by nucleic acid analysis (see abstract and columns 5 and 6, example 1).

The Appellant does not dispute that the two references teach every element of the invention with one exception. At page 6 of Appellant's response, Appellant argues that the Kreisher reference does not teach the use of nonporous materials. This argument is not, however, addressed to the claims since they lack any limitation that the matrix is nonporous. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Consequently, the feature argued to be absent is not within the claims and this argument should be found unpersuasive.

Motivation

In addressing the motivation issue, it is important to appreciate how routine and ordinary is the transfer of molecules from a matrix to a target substrate, an element taught by Kreisher. Many of the major detection method in modern molecular biology, ranging from Southern blotting to Northern and Western blotting rely upon the transfer of either nucleic acid or protein molecules from a matrix to a target substrate. Kreisher notes this in 1986, stating "Blotting or transfer of electrophoretically resolved material, such as DNA, RNA and protein, has become a standard procedure when sensitive and specific detection of biologically interesting macromolecules is requires (see column 1, lines 26-30)".

Halverson expressly suggests that "'Affix' shall include any mode of attaching reactants to a substrate. Such modes shall include, without limitation, covalent and

ionic binding, adherence, such as with an adhesive, and physical entrapment within a substrate (page 6, lines 12-14)". So when Halverson is open to any mode of attachment of DNA, RNA or protein to the laminate, one mode which would be immediately suggested by the abundance of the prior art, as represented by Kreisher, would be blotting, and in particular, electroblotting of gels onto the laminates of Halverson. Kreisher provides specific motivation to use electroblotting to transfer molecules onto supports, noting that "Therefore it is a principal advantage of the present invention to provide a rapid and efficient method for electroblotting (see column 2, lines 19-21)." Kreisher continues a sentence later to note "It is an additional object of the present invention to provide a method as aforesaid which obtains high resolution and absence of diffusion (see column 2, lines 25-27)."

Appellant's analysis of the Kreisher and Halverson references fails to properly combine the teachings of these two techniques. Halverson is interested in having biological molecules such as DNA and RNA affixed to a substrate (see page 6, lines 12-14) and Kreisher solves this affixation problem by providing a rapid and efficient mode of attaching DNA and RNA to the substrate in a manner which permits the high resolution and low diffusion necessary and desirable (see column 2 of Kreisher) in the shrinkable arrays of Halverson. Kreisher provides an excellent motivation to use electroblotting as the mode of affixation desired by Halverson.

Reasonable expectation of success

Appellant admits that the references provide a reasonable expectation of success for the use of porous materials (see page 6 of brief). Since the claims are

broad and permit the use of porous laminate materials, this would be sufficient to end this inquiry. For the current claims lack any limitation regarding porosity and consequently, Appellant's admission is sufficient to prove a reasonable expectation of success.

However, even if the Appellant's limitation were read into the claims from some source outside of the claims, there is still a reasonable expectation of success. The legal standard for "reasonable expectation of success" is provided by caselaw and is summarized in MPEP 2144.08, which notes "obviousness does not require absolute predictability, only a reasonable expectation of success; i.e. , a reasonable expectation of obtaining similar properties. See , e.g. , In re O'Farrell , 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)." In this factual case, there is express suggestion in the prior art of Kreisher that molecules can be transferred by electrophoretic means from one support to another support (see, for example, column 4, lines 7-10). This sufficient for a reasonable expectation of success. The MPEP cites In re O'Farrell, which notes regarding "obvious to try" at page 1682, that,

> "In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. E.g ., In re Geiger , 815 F.2d at 688, 2 USPQ2d at 1278; Novo Industri A/S v. Travenol Laboratories, Inc ., 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); In re Yates , 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981); In re Antonie , 559 F.2d at 621, 195 USPQ at 8-9. In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. In re Dow Chemical Co ., 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985)."

The court in O'Farrell then, affirming the rejection, notes " Neither of these situations applies here." For the instant case, it is clear that neither situations applies here either. This is not a situation where the prior art suggests varying a variety of parameters, since the prior art of Kreisher directly points to the use of electroblotting as a means of transferring molecules from one support to another. This is also not a situation where only general guidance was given. The prior art provides specific guidance directing the use of electroblotting and Halverson expressly suggests that any known means of affixing is desirable (see column 6) and Kreisher provides a known means of affixing as discussed in the rejection. Appellant's argument that a coating might have interfered with the transfer does not overcome Halverson's teaching of an expectation of success since Halveron expressly indicates that any mode of affixing would be expected to function (see column 6).

Secondary Considerations

Appellant argues no secondary considerations.

Conclusion

Therefore, since the Halverson and Kreisher references teach each and every limitation of the claimed invention and since Kreisher solves the affixation issue of Halverson by providing a rapid and efficient mode of attaching DNA and RNA to the substrate in a manner which permits the high resolution and low diffusion necessary and desirable with a reasonable expectation of success, the 35 U.S.C. 103(a) rejection should be sustained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Art Unit 1634

June 3, 2003

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